

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ahn et al.

Serial No.:

10/573,359

Filed:

3/24/2006

Group No.: not assigned

Examiner:

not assigned

Entitled:

**Process for Purifying Human Thrombopoietin** 

With High Content of Sialic Acid

# INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: February 26, 2007

Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including references, in the above-identified application, for filing in the U.\$. Patent Office.

This Information Disclosure Statement and PTO Form-1449 is being filed before the issuance of a first Office Action, therefore, Applicants believe no fee is required.

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: February 26, 2007

Tanya A. Arenson

Registration No. 47,391

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 305 San Francisco, California 94105 608/218-6900



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Alexandria, VA 22313-1450.
Date: [Rebinnary 26, 2007] By:
Many Bilen Waite!

#### Sir or Madam:

The citations listed below may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

- U.S. Patent No. 5,879,673
- U.S. Patent No. 5,696,250
- U.S. Patent No. 5,989,538
- U.S. Patent No. 5,633,162
- U.S. Patent No. 5,744,587
- WO 00/00612 A
- WO 03/057866 A

- EP 0 668 352 A
- WO 98/52598 A
- CN 1 369 507 A
- WO 95/18868
- WO95/21919
- WO 95/18858
- WO96/25498
- O'Connor, "Chromatography of recombinant proteins," Developments in Biological Standardization, 97:39-47 (1999)
- Lok et al., "Promotion of megakaryocyte progenitor expansion and differentiation by the c-Mpl ligand thrombopoietin," Nature, 369: 565-568 (1994)
- de Sauvage et al., "Stimulation of megakaryocytopoiesis and thrombopoiesis by the c-Mpl ligand," Nature, 369: 533-538 (1994)
- Miyazaki et al., Experimental hematol., 22: 828 (1994)
- Shinjo et al., "Serum thrombopoietin levels in patients correlate inversely with platelet counts during chemotherapy-induced thrombocytopenia," Leukemia, 12: 295-300 (1998)
- Pascual-Castroviejo et al., "Hypomelanosis of ITO. A study of 76 infantile cases,"
   Brain Dev 20(1): 36-43 (1998)
- Takeuchi et al., "Relationship between sugar chain structure and biological activity of recombinant human erythropoietin produced in Chinese hamster ovary cells.," Proc. Natl. Acad. Sci. USA. 86: 7819(1989)
- Morimoto, et al., "Biological and physicochemical characterization of recombinant human erythropoietins fractionated by Mono Q column chromatography and their modification with sialyltransferase," Glycoconj J.,13(6): 1013-20(1996)
- Park et al., "Identification of functionally important residues of human thrombopoietin," J. Biol. Chem., 273:256-261, 1998)

- Inoue et al., "Asn-linked sugar chain structures of recombinant human thrombopoietin produced in Chinese hamster ovary cells," Glycoconj J. 16(11):707-719 (1999)
- Kato W et al., "Purification and characterization of thrombopoietin," J Biochem 118(1):229-236 (1995)
- Kaszubska et al, "Expression, purification, and characterization of human recombinant thrombopoietin in Chinese hamster ovary cells," Protein Expression and Purification, 18:213-220 (2000)

Applicants wish to bring to the examiners attention that we are not providing copies of US Patents as instructed under 37 CFR 1.98(a)(2).

Applicants' herewith submit the Supplementary European Search Report from EP 03 75 1496.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: February 26, 2007

Tanya A. Arenson Registration No. 47,391 MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 608/218-6900

PTO/SB/08A (08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ler the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 1

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

(Use as many sheets as necessary)

Complete if Known					
Application Number	10/573,359				
Filing Date	3/24/2006				
First Named Inventor	Ahn et al.				
Art Unit	not assigned				
Examiner Name	not assigned				
Attorney Docket Number	HANOL-10524				

			U. S. PATEN	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	<sup>US-</sup> 5,879,673	03/09/1999	Roger et al.	entire document
	2	<sup>US-</sup> 5,696,250	12/09/1997	Elliott et al.	entire document
	3	US- 5,989,538	11/23/1999	Elliott et al.	entire document
	4	<sup>US-</sup> 5,633,162	05/27/1997	Keen et al.	entire document
	5	<sup>US-</sup> 5,744,587	04/28/2998	Alaska et al.	entire document
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		FORE	IGN PATENT DOCL	JMENTS		
Examiner Cite	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages		
		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ°
	6	WO 00/00612 A	01/06/2000	Chung et al.	entire document	
	7	WO 03/057866 A	07/17/2003	Lee et al.	entire document	
	8	EP 0 668 352 A	08/23/1995	Kirin Brewery	entire document	
	9	WO 98/52598 A	11/26/1998	Cohen et al.	entire document	
	10	CN 1 369 507 A	09/18/2002	Univ Nanjing	entire document	
	11	WO95/18868	07/13/1995	Cook et al.	entire document	

Examiner	Date	
Signature	Considered	•

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 2

of |4

-			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
		Number-Kind Code <sup>2 (# known)</sup>			Figures Appear
		US-			
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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	L
	12	WO95/21919	08/17/1995	Miyazuki et al	entire document	
	13	WO 95/18858	07/13/1995	Eaton et al.	entire document	
	14	WO96/25498	08/22/1996	Elliott	entire document	L
					entire document	

Examiner	Date	
Signature	Considered	

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PTO/SB/08B (08-03) Approved for use through 07/31/2006. OMB 0651-0031

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	te for form 1449/PTO				Complete if Known
Substitu	te 101 101111 1443/F 10			Application Number	10/573,359
INF	ORMATION	DIS	CLOSURE	Filing Date	3/24/2006
STATEMENT BY APPLICANT		First Named Inventor	Ahn et al.		
	41			Art Unit	not assigned
	(Use as many sh	ets as r	lecessary)	Examiner Name	not assigned
Sheet	3	of	4	Attorney Docket Number	HANOL-10524

Evemine:	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Examiner Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	15	O'Connor, "Chromatography of recombinant proteins," Developments in Biological Standardization, 97:39-47 (1999)	
	16	Lok et al., "Promotion of megakaryocyte progenitor expansion and differentiation by the c-Mpl ligand thrombopoietin," Nature, 369: 565-568 (1994)	
	17	de Sauvage et al., "Stimulation of megakaryocytopoiesis and thrombopoiesis by the c-Mpl ligand," Nature, 369: 533-538 (1994)	
	18	Miyazaki et al., Experimental hematol., 22: 828 (1994)	
	19	Shinjo et al., "Serum thrombopoietin levels in patients correlate inversely with platelet counts during chemotherapy-induced thrombocytopenia," Leukemia, 12: 295-300 (1998)	
	20	Pascual-Castroviejo et al., "Hypomelanosis of ITO. A study of 76 infantile cases," Brain Dev 20(1): 36-43 (1998)	
	21	Takeuchi et al., "Relationship between sugar chain structure and biological activity of recombinant human erythropoietin produced in Chinese hamster ovary cells.," Proc. Natl. Acad. Sci. USA. 86: 7819(1989)	
	22	Morimoto, et al., "Biological and physicochemical characterization of recombinant human erythropoietins fractionated by Mono Q column chromatography and their modification with sialyltransferase," Glycoconj J.,13(6): 1013-20(1996)	
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INFORMATION DISCLOSURE	Filing Date	3/24/2006
STATEMENT BY APPLICANT	First Named Inventor	Ahn et al.
(Use as many sheets as necessary)	Art Unit	not assigned
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Sheet 4 of 4	Attorney Docket Number	HANOL-10524

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of			
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
*	25	Kato W et al., "Purification and characterization of thrombopoietin," J Biochem 118(1):229-236 (1995)			
	26	Kaszubska et al, "Expression, purification, and characterization of human recombinant thrombopoietin in Chinese hamster ovary cells," Protein Expression and Purification, 18:213-220 (2000)			
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